SIEMENS

Section 006: 510(k) Summary

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: k140267

1. **Applicant Information**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591 USA
Contact Person:	Fatima Pacheco Regulatory Clinical Affairs Specialist
Phone Number:	(914) 524-2450
Fax Number:	(914) 524-3579
E-mail Address:	fatima.pacheco@siemens.com
Date Prepared:	January 29, 2014

2. **Device Name**

Proprietary Name:	**ADVIA Centaur® TnI-Ultra® Master Curve Material**
Measurand:	Quality Control materials for ADVIA Centaur TnI-Ultra assay
Type of Test:	Master Curve Material (MCM) for ADVIA Centaur TnI-Ultra assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name** — Elecsys Troponin I CalCheck 5
   Predicate 510(k) No: k100594

4. **Device Description:** ADVIA Centaur® TnI-Ultra® Master Curve Material is an *in vitro* diagnostic product containing various levels of bovine cardiac troponin I in a goat serum matrix with preservatives. Each set contains five lyophilized levels (MCM1–5); with a reconstituted volume of 1.0 mL each. MCM1contains no analyte. The TnI-Ultra MCMs assigned values are lot-specific

	of target values 0.00, 1.00, 3.50, 14.0 and 40.0 ng/mL.
5. **Intended Use:** **Indication for Use:**	See Indications for Use Statement below: The ADVIA Centaur TnI-Ultra Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur TnI-Ultra assay.
Special Conditions for Use Statement(s):	For prescription use only
Special Instrument Requirements:	ADVIA Centaur® Systems A description of the ADVIA Centaur system is documented in K971418. Subsequent modifications to the instrument have been reviewed and cleared in K032525 and K041133
6. **Technological Characteristics and Substantial Equivalence Comparison with Predicate:**	A comparison of the device features, intended use, and other information demonstrates that the ADVIA Centaur TnI-Ultra MCM is substantially equivalent to the predicate device as summarized in **Table 1**.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device	**Predicate Device**
Item	ADVIA Centaur TnI-Ultra MCM	Elecsys Troponin I CalCheck 5
Intended Use	The ADVIA Centaur TnI-Ultra Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur TnI-Ultra assay.	The Elecsys Troponin I CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Troponin I reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Analyte	Troponin I	Same
Form	Lyophilized	Same
Use	Multiple Use	Same
Levels	5	Same
Storage	2–8°C	Same
DIFFERENCES		
Matrix	Goat Serum	Human Serum
Stability	**Unopened** – Stable when stored unopened at 2–8°C until the expiration date on the vial label. **Opened (Reconstituted)** – Stable when stored at 2–8°C for 8 hours; or on-board for 4 hours; or when stored at -20°C for 60 days.	**Unopened** – Stable at 2–8°C up to the expiration date printed on the bottle labels. **Reconstituted** – Stable for 4 hours at 20–25°C.

7. **Standard/Guidance Document References**

The following recognized standard and guidance documents were used:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

8. Test Principle

The MCMs are specifically intended for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur assays for use on the ADVIA Centaur systems. Customers use MCMs for bi-annual calibration verification checks of the assay range and linearity in order to meet the requirements of hospital accreditation bodies.

9. Performance Characteristics

9.1 Analytical performance:

The following studies are not applicable for the purpose of this submission:

- *Precision/Reproducibility*
- *Linearity/Assay Reportable Range*
- *Detection limit*
- *Analytical Specificity*
- *Assay cut-off*
- *Method Comparison Studies*
- *Clinical Studies (Sensitivity, Specificity, and cut-off)*

9.2 Non-Clinical Performance Testing

9.2.1 *Stability Studies*

Stability studies were conducted to support the shelf life unopened and reconstituted material for the ADVIA Centaur TnI-Ultra MCMs to ensure that it maintains optimal product performance throughout the established shelf-life. The data supports the stability claims detailed in the ADVIA Centaur TnI-Ultra MCM Instructions for Use.

The following stability studies were performed for ADVIA Centaur TnI-Ultra MCM:

- Real Time/Shelf Life (unopened)
- In Use (open vial) storage at 2–8°C (reconstituted)
- In Use (open vial) storage at -20°C (reconstituted)
- On-Board

Real time shelf-life studies (unopened): Test TnI-Ultra MCMs were stored unopened at 2–8°C and tested at T=0 and at the following time points: 3 months, 6 months, and 10 months. Shelf life claims are based upon real time stability carried out one month after the duration claimed. Real time shelf-life stability studies of MCMs were determined by comparison of dose recoveries to the T=0 dose recovery results. Acceptance criteria for the real-time stability study were met up to the 10 months time point, which supports a shelf-life claim of 9 months. Unopened storage shelf-life is indicated by expiration date on the vial label.

In use open vial (reconstituted) stored at 2–8°C: Test TnI-Ultra MCMs were reconstituted, each level pooled, aliquotted and stored at 2–8°C, tested in 5 replicates per level at T=0, 2, 4, 6, 8, 9, 24 and 25 hours. Acceptance criteria for the open vial (reconstituted) stability study were met up to the 9 hour time point, which supports the open vial claim of 8 hours when stored at 2–8°C.

In use open vial (reconstituted) stored at -20°C: Test TnI-Ultra MCMs were reconstituted, each level pooled, aliquotted and stored at -20°C, tested in 5 replicates per level at Day=0, 14, 28, 35,45, 60 and 63days. Acceptance criteria for the open vial (reconstituted) stability study were met up to the 63days time point, which supports the open vial (reconstituted) claim stored -20°C for 60 days.

On-board Stability: Test TnI-Ultra MCMs were reconstituted, each level pooled, aliquotted into sample cups and stored on the ADVIA Centaur system and measured at time point T= 0, 2, 4 and 5 hours. Acceptance criteria for the on-board stability study were met up to 5 hours, which supports the on-board stability claim for 4 hours.

Stability Acceptance Criteria

The stability specifications acceptance criteria for the ADVIA Cenatur TnI-Ultra MCM are as follows:

- Real Time/Shelf life (Unopened): The dose recovery for MCM1 must be ≤ 0.02 dose and for MCM2–5, the % dose recovery must be within 85 to 115% calculated to Day 0 and/or no adverse trends.
- In Use (Open Vial) storage at 2–8°C (reconstituted): The dose recovery for MCM1 versus freshly reconstituted -80°C stored MCM1 average dose must be ≤ 0.02 dose and for MCM 2–5 versus freshly reconstituted -80°C stored MCM2–5 average dose, the % dose recovery must be within 85 to 115%.
- In Use (Open Vial) storage at -20°C (reconstituted): The dose recovery for MCM1 versus freshly reconstituted -80°C stored MCM1 average dose must be ≤ 0.02 dose and for MCM 2–5 versus freshly reconstituted -80°C stored MCM2–5 the average % dose recovery must be within 85 to 115%.
- On-Board: The dose recovery for MCM1 must be ≤ 0.02 dose and for MCM2–5 the % dose recovery must be within 85 to 115% calculated to Time=0.

9.2.2 *Value Assignment*

The ADVIA Centaur TnI-Ultra MCMs are value assigned using assigned reference calibrators and MCMs. The assigned reference calibrators are prepared using bovine troponin I antigen stock and are traceable to highly purified internal material. The MCMs are manufactured using qualified materials and measurement procedures.

For each new TnI-Ultra MCM lot manufactured, MCM1 is run in 5 replicates on two separate runs using one reagent kit lot. A nested testing run protocol is used for MCM2–MCM5 value assignment. This consists of running alternating samples of the reference and new MCM level in the same run. MCM2–MCM5 were tested on 20 replicates in total, comprised of one run and four sample cups run in 5 replicates on one system and one reagent kit lot. This protocol is designed to remove system and run variation. The new MCM doses must fall within the final value assignment specification for TnI-Ultra MCMs. A performance verification run consisting of 6 replicates of each MCM level is run using one instrument, one reagent kit lot and Bio-Rad Cardiac controls. The mean MCM doses of the new TnI-Ultra MCM lot manufactured must fall within the release range specifications. The release ranges are 5% tighter than the customer ranges.

The target for MCM1 is assigned a 0.0 dose. There is no statistical method used to assign the 0.0 dose. MCM1 range is claimed as "< " less than 3X the limit of sensitivity (≤ 0.018 ng/mL) of the ADVIA Centaur TnI-Ultra assay.

9.2.3 *Expected Values*

The expected values are the lot-specific assigned values obtained at value assignment and the lot-specific assigned ranges are the lot-specific customer ranges established per % interval as below.

MCM Level	% Interval
MCM1	N/A
MCM2	20%
MCM3	20%
MCM4	20%
MCM5	20%

Lot-specific assigned values and ranges are provided in the ADVIA Centaur TnI-Ultra MCM lot-specific value sheet example as below in Table 2.

Table 2: Example Lot-specific Assigned Values and Ranges for TnI-Ultra MCM

MCM level	Target Values (ng/mL)	Assigned Values (ng/mL)	Range (ng/mL)
MCM1	0	0.00	< 0.018
MCM2	1.00	0.612	0.490–0.734
MCM3	3.50	3.24	2.59–3.89
MCM4	14.0	12.2	9.76–14.6
MCM5	40.0	32.5	> 26.0
Assay Range	0.006–50 ng/mL		

9.2.4 *Traceability*

The ADVIA Centaur TnI-Ultra assay is traceable to NIST SRM 2921. The ADVIA Centaur TnI-Ultra assay is standardized to an internal standard manufactured using highly purified material. Assigned values for calibrators and MCMs are traceable to this standardization. The TnI-Ultra MCMs are manufactured using qualified materials and measurement procedures.

10. Proposed Labeling

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

11. Conclusion

The ADVIA Centaur TnI-Ultra Master Curve Material (MCM) is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys Troponin I CalCheck 5. Based on the testing completed and the comparisons with predicate device, the ADVIA Centaur TnI-Ultra Maser Curve Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

K140267

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: k140267

1. **Applicant Information**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591 USA
Contact Person:	Fatima Pacheco Regulatory Clinical Affairs Specialist
Phone Number:	(914) 524-2450
Fax Number:	(914) 524-3579
E-mail Address:	fatima.pacheco@siemens.com
Date Prepared:	January 29, 2014

2. **Device Name**

Proprietary Name:	**ADVIA Centaur® Digoxin Master Curve Material**
Measurand:	Quality Control materials for ADVIA Centaur Digoxin assay
Type of Test:	Master Curve Material (MCM) for ADVIA Centaur Digoxin assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name** — Elecsys Dogixin CalCheck 5
Predicate 510(k) No: k102044

4. **Device Description:** ADVIA Centaur® Digoxin Master Curve Materials is an *in vitro* diagnostic product containing various levels of digoxin in defibrinated human plasma with sodium azide (0.1% after reconstitution) and preservatives. Each set contains six lyophilized levels (MCM1–6); with a reconstituted volume of 1.0 mL each. MCM1 contains no analyte. The Digoxin MCMs assigned values are lot specific of target values 0.0, 0.50, 1.00, 2.00, 3.00, 5.50 ng/mL.

CAUTION! POTENTIAL BIOHAZARD: Contains human source material. While each human serum or plasma donor unit

	used in the manufacture of this product was tested by FDA-approved methods and found nonreactive for hepatitis B surface antigen (HBsAg), antibody to hepatitis C (HCV), and antibody to HIV-1/2, all products manufactured using human source material should be handled as potentially infectious. Because no test method can offer complete assurance that hepatitis B or C viruses, HIV, or other infectious agents are absent, these products should be handled according to established good laboratory practices.
5. **Intended Use:** **Indication for Use:**	See Indications for Use Statement below: The ADVIA Centaur® Digoxin Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Digoxin assay.
Special Conditions for Use Statement(s):	For prescription use only
Special Instrument Requirements:	ADVIA Centaur® Systems A description of the ADVIA Centaur system is documented in K971418. Subsequent modifications to the instrument have been reviewed and cleared in K032525 and K041133.
6. **Technological Characteristics and Substantial Equivalence Comparison with Predicate:**	A comparison of the device features, intended use, and other information demonstrates that the ADVIA Centaur Digoxin MCM is substantially equivalent to the predicate device as summarized in **Table 1**.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device	**Predicate Device**
Item	ADVIA Centaur Digoxin MCM	Elecsys Digoxin CalCheck 5
Intended Use	The ADVIA Centaur Digoxin MCM is for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Digoxin assay.	The Elecsys Digoxin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Digoxin reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Analyte	Digoxin	Same
Use	Multiple Use	Same
Storage	2–8°C	Same
DIFFERENCES		
Form	Lyophilized	Liquid
Matrix	Defibrinated human plasma	Bovine Serum
Levels	6	5
Stability	**Unopened** – Stable when stored unopened at 2–8°C until the expiration date on the vial label. **Opened (Reconstituted)** – Stable when stored at 2–8°C for 28 days; or on-board for 4 hours.	**Unopened** – Stable at 2–8°C up to the expiration date printed on the bottle labels. **Opened** – Stable for 5 hours at 20–25°C.

7. Standard/Guidance Document References

The following recognized standard and guidance documents were used:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – **Abbreviated** 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

8. **Test Principle**

The MCMs are specifically intended for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur assays for use on the ADVIA Centaur systems. Customers use MCMs for bi-annual calibration verification checks of the assay range and linearity in order to meet the requirements of hospital accreditation bodies.

9. **Performance Characteristics**

9.1 Analytical performance:

The following studies are not applicable for the purpose of this submission:

- *Precision/Reproducibility*
- *Linearity/Assay Reportable Range*
- *Detection limit*
- *Analytical Specificity*
- *Assay cut-off*
- *Method Comparison Studies*
- *Clinical Studies (Sensitivity, Specificity, and cut-off)*

9.2 Non-Clinical Performance Testing

9.2.1 ***Stability Studies***

The stability studies were conducted to support the shelf life (unopened) and opened reconstituted material for the ADVIA Centaur Digoxin MCMs. The data supports the stability claims detailed in the ADVIA Centaur Digoxin MCM Instructions for Use.

The following stability studies were performed for ADVIA Centaur Digoxin MCM:

- Real Time/Shelf Life (unopened)
- In Use (open vial) storage at 2–8°C (reconstituted)
- On-Board Stability

Real time shelf-life studies (unopened): Test Digoxin MCMs were stored unopened at 2–8°C and tested at T=0 and at the following time points: 12 months, 18 months, and 33 months. Shelf life claims are based upon real time stability carried out one month after the duration claimed. Real time shelf-life stability studies of MCMs were determined by comparison of dose recoveries to the T=0 dose recovery results. Acceptance criteria for the real-time stability study were met up to the 33 months' time point, which supports a shelf-life claim of 32 months. Unopened storage shelf-life is indicated by expiration date on the vial label.

In use open vial (reconstituted) stored at 2–8°C: Test Digoxin MCMs were reconstituted, each level pooled, aliquotted and stored at 2–8°C, tested in 5 replicates per level at T=0, 7, 14, 21, 28 and 29 days. Acceptance criteria for the open vial (reconstituted) stability study were met up to the 29 days' time point, which supports the open vial claim of 28 days when stored at 2–8°C.

On-board Stability: Test Digoxin MCMs were reconstituted, each level pooled, aliquotted into sample cups and stored on the ADVIA Centaur system and

measured at time point T= 0, 2, 4 and 5 hours. Acceptance criteria for the on-board stability study were met up to 5 hours, which supports the on-board stability claim for 4 hours.

Stability Acceptance Criteria

The stability specifications acceptance criteria for the ADVIA Centaur Digoxin MCM are as follows:

- Real Time/Shelf life (Unopened): The dose recovery for MCM1 must be ≤ 0.10 dose, for MCM2 the % dose recovery must be within 82 to 118% and for MCM3–6 the % dose recovery must be within 85 to 115% calculated to Day 0 and/or no adverse trends.
- In Use (Open Vial) storage at 2–8°C (reconstituted): The dose recovery for MCM1 versus -80°C stored MCM1 average dose must be ≤ 0.10 dose, for MCM2 versus -80°C stored MCM2 average dose the % dose recovery must be within 82 to 118% and for MCM 3–6 versus -80°C MCMs 3–6 average dose the % dose recovery must be within 85 to 115%.
- On-Board Stability: The dose recovery for MCM1 must be ≤ 0.10 dose, for MCM2 the % dose recovery must be within 82 to 118% and for MCM3–6 the % dose recovery must be within 85 to 115% calculated to T=0.

9.2.2 Value Assignment

The ADVIA Centaur Digoxin MCMs are value assigned using assigned reference calibrators and MCMs. The assigned reference calibrators are prepared using USP (United States Pharmacopeia) Digoxin stock and are traceable to USP internal material. The MCMs are manufactured using qualified materials and measurement procedures.

For each new Digoxin MCM lot manufactured, MCM1 is run in 5 replicates on two separate runs using one reagent kit lot. A nested testing run protocol is used for MCM2–MCM6 value assignment. This consists of running alternating samples of the reference and new MCM level in the same run. MCM2–MCM6 were tested on 20 replicates in total, comprised of one run and four sample cups run in 5 replicates on one system and one reagent kit lot. This protocol is designed to remove system and run variation. The new MCM doses must fall within the final value assignment specification for Digoxin MCMs. A performance verification run consisting of 6 replicates of each MCM level is run using one instrument, one reagent kit lot and Bio-Rad controls. The mean MCM doses of the new Digoxin MCM lot manufactured must fall within the release range specifications. The release ranges are 5% tighter than the customer range specifications.

The target for MCM1 is assigned a 0.0 dose. There is no statistical method used to assign the 0.0 dose. MCM1 range is claimed as "<" less than 3X the limit of sensitivity (≤ 0.1 ng/mL) of the ADVIA Centaur Digoxin assay. MCM6 is targeted greater than the assay range, customers need to dilute with MCM1 to meet the reportable range of the assay.

9.2.3 *Expected Values*

The expected values are the lot-specific assigned values obtained at value assignment and the lot-specific assigned ranges are the lot-specific customer ranges established per % interval as below.

MCM Level	% Interval
MCM1	N/A
MCM2	40%
MCM3	20%
MCM4	20%
MCM5	20%
MCM6	20%

Lot-specific assigned values and ranges are provided in the ADVIA Centaur Digoxin MCM lot-specific value sheet example as below in **Table 2.**

Table 2: *Example Lot-specific Assigned Values and Ranges for Digoxin MCM*

MCM level	Target Values (ng/mL)	Assigned Values (ng/mL)	Range (ng/mL)
MCM1	0.00	0.032	< 0.300
MCM2	0.500	0.574	0.344–0.804
MCM3	1.00	1.12	0.896–1.34
MCM4	2.00	2.14	1.71–2.57
MCM5	3.00	3.14	2.51–3.77
MCM6	5.50	5.53	> 4.42
Assay Range	0.1–5.0 ng/mL		

9.2.4 *Traceability*

The ADVIA Centaur Digoxin assay is standardized to an internal standard manufactured using USP (United States Pharmacopeia) material. Assigned values for calibrators and MCMs are traceable to this standardization.

10. Proposed Labeling

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

11. Conclusion

The ADVIA Centaur Digoxin Master Curve Material (MCM) is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys Digoxin CalCheck 5. Based on the testing completed and the comparisons with predicate device, the ADVIA Centaur Digoxin Maser Curve Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 10, 2014

SIEMENS HEALTHCARE DIAGNOSTICS INC.
FATIMA PACHECO
REGULATORY CLINICAL AFFAIRS SPECIALIST
511 BENEDICT AVENUE
TARRYTOWN NY 10591-5097

Re: K140267
Trade/Device Name: ADVIA Centaur TnI-Ultra® Master Curve Material (MCM), ADVIA Centaur® Digoxin Master Curve Material (MCM)
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: I, reserved
Product Code: JJX
Dated: February 04, 2014
Received: February 7, 2014

Dear Ms. Pacheco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
k140267

Device Name
ADVIA Centaur® TnI-Ultra® Master Curve Material (MCM)

Indications for Use *(Describe)*
The ADVIA Centaur® TnI-Ultra® Master Curve Material is for in vitro diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur TnI-Ultra assay.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ruth A. Chesler -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

k140267

Device Name

ADVIA Centaur® Digoxin Master Curve Material (MCM)

Indications for Use *(Describe)*

The ADVIA Centaur® Digoxin Master Curve Material is for in vitro diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Digoxin assay.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ruth A. Chesler -S

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."